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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,811	03/26/2004	Nagaraja Rao Ramesh Mysore	US 1375/04	7940

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EXAMINER	
SCHUBERG, LAURA J	

ART UNIT	PAPER NUMBER
1657	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/809,811	MYSORE ET AL.	
	Examiner	Art Unit	
	Laura Schuberg	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *09 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 10-27* is/are rejected.

7)☒ Claim(s) *1, 6, 8, 10, 19, 22, 27* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/9/04, 4/9/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of species submerged fermentation process in the reply filed on 04/09/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-27 are pending.

Claim 9 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected specie, there being no allowable generic or linking claim.

Claims 1-8 and 10-27 have been examined on the merits.

Claim Objections

Claims 1, 6, 8, 10, 19, 22, 27 are objected to because of the following informalities:

In claims 19 and 22, the term "upto" should be two words.

In claim 27 the term "atleast" should be two words.

In claims 1, 6, 8, 10, Fructosyl Transferase has been abbreviated as Ftase or FTase. For consistency, a single abbreviation should be used.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 8, 20, 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the culture" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 8 recites the limitation "the pellets" in line 6. There is insufficient antecedent basis for this limitation in the claim.

Claim 8 recites two ranges for the K_2HPO_4.

Claim 20 recites the limitation "FOS powder" in line 1. There is insufficient antecedent basis for this limitation in the claim since claim 1 does not include production of FOS powder.

Claim 20 recites the limitation "weeks in the range of 5 to 5" in line 2. It is unclear whether 5 is intended to be the upper or lower amount. For examination purposes the number of weeks is interpreted to be about 5.

Claim 22 recites the limitation "during either before or after spray drying" in line 4. There is insufficient antecedent basis for this limitation in the claim as far as it is dependent upon claim 1 since claim 1 does not have a spray drying step.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 10-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Sangeetha et al (Sciences Des Aliments 2002).

Claim 1 is drawn to a process for obtaining FOS comprising: a) growing a culture in a medium at 5-6 pH, 25-30 degrees C under stirring conditions to obtain an inoculum, b) transferring the inoculum to a medium under fermentation conditions to obtain Ftase, c) incubating the Ftase with 400-800 g/L of a substrate at pH 5 to 5.5 for 18 to 24 hours at 50 to 55 degrees C and d) optionally along with additives to improve quality of FOS.

Claim 2 includes wherein the medium in step a) consists of sucrose in the range of 0.8 to 1.5% and yeast extract in the ranges of 0.1 to 0.5 %.

Claim 3 includes wherein the stirring in step a) is done at 200 to 250 rpm for 24-48 hours.

Claim 4 includes wherein the culture used in step a) is selected from the group consisting of *Aspergillus oryzae* and *Aspergillus pullulans*, capable of producing Ftase.

Claim 5 includes wherein the inoculum used is developed from 5 to 8 days old slant culture.

Claim 6 includes wherein the Ftase is prepared by fermentation process selected from the group consisting of submerged fermentation and solid state fermentation (Applicant elected submerged fermentation).

Claim 7 includes wherein the predetermined concentration of the inoculum varies in the range of 10 to 25% (v/v) for submerged fermentation.

Claim 8 includes specific concentrations for the submerged fermentation medium and specific incubation and temperature ranges followed by discarding the pellets after filtering the culture broth to obtain Ftase.

Claim 10 includes wherein the substrate is selected from a group consisting of sucrose, jaggery optionally along with stevia extract as an additive to improve sweetness.

Claims 11 and 12 include specific concentrations for the stevia extract.

Claims 13 and 14 include wherein the sweetness in FOS is increased a specific amount.

Claims 15-20 include functional properties of the FOS produced.

Sangeetha teaches a method for the production of Ftase and FOS and the influence of media components and reaction parameters. A culture of Aspergillus oryzae was prepared by transferring spores from a 5 day old slant to medium containing 1% sucrose and 0.2% yeast extract at pH 5.5 and incubated at 30 degrees C on rotary shaker (stirring conditions) at 250 rpm for 24 hours (page 279 part 2.2) to produce Ftase. Submerged fermentation is taught (page 279 part 2.3 and page 286 line 6) as well as discarding the pellets after filtering the culture broth to obtain Ftase and wherein the concentration of the inoculum is 10% (page 281 table 1). FOS production was carried out by incubation of the Ftase with sucrose as the substrate (page 280 part 2.5). Since the FOS yields are 21.5g/L to 435.68 g/L corresponding to 4.3% to 54.46% (w/w) of the initial sucrose, respectively, the concentration of the substrate (sucrose) ranged

from 400 to 800 g/L (page 282 part 3.1). Sangeetha teaches wherein the pH of the substrate and the medium is 5.5, wherein the reaction time is 18 hours and wherein the temperature is 55 degrees C (page 281 table 1). Wherein the submerged fermentation medium consists of sucrose at 10%, yeast extract at 0.8%, $MgSO_47H_20$ at 0.02%, $NaNO_3$ at 1.0 and 3.0%, K_2HPO_4 at 0.5%, NaCl at 0.5%, NH_4Cl at 1.0% and incubated for 48 to120 hours (page 281 table 1) at a temperature of 30 degrees C (page 279 part 2.3) is taught.

While the reference does not specifically teach the functional properties of the FOS produced (as cited in claims 15-20), these properties are deemed inherent since the production method of the reference FOS has the same steps as the claimed method.

All limitations indicated as optional, such as additives and stevia extract (claims 1 and 10-14), are not required for the method as claimed.

Therefore, the teachings of Sangeetha anticipate Applicant's invention as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sangeetha et al (Sciences Des Aliments 2002) as applied to claims 1-8, 10-20 above, and further in view of Vijayendra et al. (Process Biochemistry 2001).

Sangeetha teaches the process for obtaining FOS as described above, but does not specifically mention using jaggery as the substrate. Sangeetha does teach that *Aureobasidium pullulans* is a suitable microbial source for production of Ftase and FOS (page 278 part 1 paragraph 3).

Vijayendra teaches jaggery is a suitable substitute for sucrose in the fermentation of *Aureobasidium pullulans* (page 262 part 4) and that jaggery is a good carbon source to support the growth as well as the production of byproducts (page 361 part 3.2).

Therefore, it would have been obvious to substitute jaggery for sucrose as the substrate in the method of Sangeetha because Vijayendra teaches that jaggery is a suitable substitute for sucrose as a carbon source for Aureobasidium pullulans. One of ordinary skill in the art would have been motivated with a reasonable expectation of success because Sangeetha teaches that *Aureobasidium pullulans* may also be used to

produced Ftase and FOS and Vijayendra teaches that *Aureobasidium pullulans* grows well with jaggery.

Therefore, the combined teachings of Sangeetha and Vijayendra render obvious Applicant's invention as claimed.

Claims 1 and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sangeetha et al (Sciences Des Aliments 2002) as applied to claims 1-8, 10-20 above, and further in view of Brouwers (US 2002/0065245).

Sangeetha teaches the process for obtaining FOS as described above, but does not specifically mention the addition of stevia extract to the substrate and Ftase. Sangeetha teaches that FOS finds numerous applications such as beverages and food products (page 278 part 1).

Brouwers teaches that FOS (page 2 para 21) and stevia extract are suitable additions to a composition that is ideal for food products for sweetening and extension of storage life. Brouwers teaches that the addition of stevia extract to gluco-oligo-saccharides provides a composition with an improved taste and improved digestive qualities. Another advantage is the stability of the final product, which is heat resistant and has an adjustable sweetening proportion per volume-unity (page 1 para 8). Brouwers also teaches that stevia has no pronounced effect on the activity of principal sugar-metabolizing enzymes and this was tested by measuring the enzyme activities with the natural substrates and in the presence of varying concentrations of stevia (page 2 para 25-28).

Therefore, one of ordinary skill in the art would have been motivated to add stevia extract to the substrate in the method of Sangeetha because Brouwers teaches that the addition of stevia extract provides numerous advantages such as improved taste, digestive qualities, extension of storage life and heat resistance. One of ordinary skill in the art would have also been motivated by Sangeetha's teaching that FOS is used for beverages and food products that would also benefit from these advantages and that Brouwers teaches that FOS is a sugar with a low sweetening capacity that is suitable for combination with stevia. One of ordinary skill in the art would have had a reasonable expectation of success in adding stevia to the substrate because Brouwers teaches that stevia has no pronounced effect on the activity of principal sugar-metabolizing enzymes and this was tested by measuring the enzyme activities with the natural substrates and in the presence of varying concentrations of stevia (page 2 para 25-28). The lowering of the concentration of stevia extract to 1% would have been a matter of routine optimization, the ordinary artisan realizing that in some situations compositions wherein the increase in sweetness is about 36 to 40% would be desired.

Therefore, the combined teachings of Sangeetha and Brouwers render obvious Applicant's invention as claimed.

Claims 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sangeetha et al (Sciences Des Aliments 2002) as applied to claims 1-8, 10-20 above, and further in view of Schlyter et al. (US 2004/0043043) and Wong (US 2004/0208981).

Claim 21 includes wherein the FOS powder is obtained by spray drying with specific inlet and outlet temperatures and flow rate.

Claim 22 includes wherein the FOS additives are selected from a group consisting of maltodextrin ranging up to 15% and anti-caking agents namely tri-calcium phosphate ranging up to 2% during either before or after spray drying.

Claim 23 includes wherein the FOS powder has a specific dry matter content, ash content and solubility.

Claim 24 includes wherein the additives improve the storage stability and the heat sensitivity of the FOS powder.

Claim 25 includes a specific yield of FOS powder.

Sangeetha teaches the process for obtaining FOS as described above, but does not specifically mention spray drying FOS.

Schlyter teaches a method of spray drying a composition that contains FOS (page 4 para 45). Schlyter teaches that spray drying is a preferred technology due to it being less expensive and more suitable for high volumes. Schlyter teaches an air inlet temperature of 100-180 degrees C with an outlet air temperature of 60-100 degrees C (page 8 para 102). Optionally, particulates of sucrose or maltodextrin are also added as well as other suitable food supplements (page 8 para 102-107). A flow rate of 135 kg/h is also taught (page 16 para 211).

Wong teaches a method of spray drying a sugar composition such as fructo-oligosaccharides (page 3 para 58) in which the dry matter content is 90-99% (page 3 para 67) or the residual humidity is lower than 1% by weight (page 3 para 66). Wong

also teaches that the composition may also include maltodextrins (page 3 para 57) and that the ash content is preferably below 4% (page 1 para 4). Agents are taught to be added that have the advantage of increasing the solubility of the components of the composition (page 2 para 28). The inlet temperature is taught to be fixed based on the flow rate in that the higher the flow rate, the higher the temperature must be due to a greater requirement for thermal energy in order to carry out drying (page 3 para 70).

Therefore, one of ordinary skill in the art would have been motivated to spray dry the FOS from the method of Sangeetha because Schlyter and Wong teach that this is a suitable method for drying FOS to produce a powder formulation suitable for food compositions. One of ordinary skill in the art would have been motivated to use an air inlet temperature of 100-180 degrees C with an outlet air temperature of 60-100 degrees C because Schlyter teaches that these are suitable for spray drying a sugar composition containing FOS. One of ordinary skill in the art would have been motivated to add maltodextrin at 2.5% because both Schlyter and Wong teach that it is advantageous to add maltodextrin and Wong teaches that 2.5 % is a suitable concentration (page 4 para 88). One of ordinary skill in the art would have been motivated to adjust the dry matter content and the ash content to about 98.6% and less than 4% respectively because Wong teaches that these are suitable amounts for a FOS powder. The flow rate would have been a matter of routine optimization based on the inlet temperature since Wong teaches that the higher the flow rate, the higher the temperature must be due to a greater requirement for thermal energy in order to carry out drying (page 3 para 70). The solubility of the FOS powder would also be a matter of

routine optimization since Wong teaches that it is desirable to include additives that increase the solubility of the composition (page 2 para 28). Addition of optional additives to improve the storage stability and reduce the heat sensitivity are taught by both Schlyter and Wong as well. The yield of the FOS powder would also have been a matter of routine optimization. One of ordinary skill in the art would have had a reasonable expectation of success because Wong and Schlyter are both teaching the spray drying of sugar compositions containing FOS for use in food.

Therefore, the combined teachings of Sangeetha, Schlyter and Wong render obvious Applicant's invention as claimed.

Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sangeetha et al (Sciences Des Aliments 2002) as applied to claims 1-8, 10-20 above, and further in view of Jonniaux et al (US 6,518,047).

Claim 26 includes wherein the culture is recycled for production of FOS.

Claim 27 includes wherein the culture is recycled at least 6 times for production of FOS.

Sangeetha teaches the process for obtaining FOS as described above, but does not specifically mention recycling the culture for production of FOS.

Jonniaux teaches that whole cells, cell extracts, cell-free extracts, enzyme preparations or purified enzymes may be immobilized by any conventional means to

allow for recycling (column 6 lines 46-63). *Aspergillus oryzae* is taught as one of the cultures used for the enzyme preparation (column 1 lines 26-35).

Therefore, one of ordinary skill in the art would have been motivated to recycle the culture of *Aspergillus oryzae* in the method of Sangeetha because recycling of the culture would have allowed for the most efficient use of resources and Jonniaux teaches that it is known to do this for enzyme or cell preparations. The number of times for recycling would have been a matter of routine optimization. One of ordinary skill in the art would have had a reasonable expectation of success because Jonniaux teaches that Aspergillus oryzae is a suitable culture for recycling.

Claims 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sangeetha et al (Sciences Des Aliments 2002), in view of Schlyter et al. (US 2004/0043043) and Wong (US 2004/0208981) as applied to claims 21-25 above, and further in view of Jonniaux et al (US 6,518,047).

Sangeetha teaches the process for obtaining FOS as described above, but does not specifically mention recycling the culture for production of FOS.

Jonniaux teaches that whole cells, cell extracts, cell-free extracts, enzyme preparations or purified enzymes may be immobilized by any conventional means to allow for recycling (column 6 lines 46-63). *Aspergillus oryzae* is taught as one of the cultures used for the enzyme preparation (column 1 lines 26-35).

Therefore, one of ordinary skill in the art would have been motivated to recycle the culture of *Aspergillus oryzae* in the method of Sangeetha because recycling of the

culture would have allowed for the most efficient use of resources and Jonniaux teaches that it is known to do this for enzyme or cell preparations. The number of times for recycling would have been a matter of routine optimization. One of ordinary skill in the art would have had a reasonable expectation of success because Jonniaux teaches that Aspergillus oryzae is a suitable culture for recycling.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Schuberg whose telephone number is 571-272-3347. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leon B Lankford, Jr
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Laura Schuberg